COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13/04/1999

C(1999) 939

NOT FOR PUBLICATION

COMMISSION DECISION

of 13/04/1999
granting the marketing authorization for the medicinal product for human use,

"CETROTIDE - Cetrorelix (as acetate)"

Only the German text is authentic

COMMISSION DECISION

of 13/04/1999
granting the marketing authorization for the medicinal product for human use,

"CETROTIDE - Cetrorelix (as acetate)"

Only the German text is authentic

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], and in particular Article 10(1) and (2) thereof,

Having regard to the application submitted by ASTA Medica Aktiengesellschaft, on 27 February 1998, under Article 4(1) of Regulation (EEC) No 2309/93, concerning the medicinal product, "CETROTIDE - Cetrorelix (as acetate)",

Having regard to the opinion of 17 December 1998 of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products,

Whereas the medicinal product, "CETROTIDE - Cetrorelix (as acetate)", complies with the requirements of Council Directives 65/65/EEC[2], 75/318/EEC[3] and 75/319/EEC[4], as last amended by Directive 93/39/EEC[5];

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

---

[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ No 22, 9.2.1965, p. 369/65.
[3] OJ No L 147, 9.6.1975, p. 1.
[4] OJ No L 147, 9.6.1975, p. 13.
[5] OJ No L 214, 24.8.1993, p. 22.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "CETROTIDE - Cetrorelix (as acetate)" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the numbers:

EU/1/99/100/001	CETROTIDE – 0.25 mg - Powder and solvent for solution for injection - 1 glass vial and 1 pre-filled syringe with solvent - Subcutaneous use
EU/1/99/100/002	CETROTIDE – 0.25 mg - Powder and solvent for solution for injection - 7 glass vials and 7 pre-filled syringes with solvent - Subcutaneous use
EU/1/99/100/003	CETROTIDE - 3 mg - Powder and solvent for solution for injection - 1 glass vial and 1 pre-filled syringe with solvent - Subcutaneous use

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and/or importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to ASTA Medica Aktiengesellschaft, An der Pikardie 10, 01227 Dresden, Deutschland.

Done at Brussels, 13/04/1999

For the Commission

Martin BANGEMANN
Member of the Commission